Decree of the Authority's President No. (642) of 2021 on Data of the Labels of Medical and Laboratory Supplies, Devices, Diagnostic Reagents, Production Components and Inputs

President of the Egyptian Drug Authority,

Having perused:

- Law No. (127) of 1955 on Pharmacy Profession Practice and its amendments;
- Law on Establishing the Egyptian Drug Authority No. (151) of 2019; and its Executive Regulation;
- The minutes of the Authority's Board of Directors meeting held in its session on 7/20/2020;
- The report of the committee formed to set the provisions for the minimum data that must be recorded on the labels of supplies, medical and laboratory devices and diagnostic reagents;
- Material presented by the chairperson of the Central Administration of Medical Devices;
- Material presented by the chairperson of the Central Administration of Operations and the chairperson of the Central Administration of Medical Devices;
- Having considered the interest of work;

Has decided

(Article One)

This decision shall be apply on the data of labels of the medical and laboratory supplies, devices, diagnostic reagents and production components and inputs.

(Article Two)

The owner of the registration notification shall be obligated to write down the mandatory data in Arabic language on the labels of the medical and laboratory supplies and devices and diagnostic reagents for the purpose of circulation in the Arab Republic of Egypt, the components and inputs of production that are imported for the purpose of use in production. The English language may be used after submitting acceptable justifications to the competent department of the Egyptian Drug Authority.

Mandatory data is divided into: Data related to the item; Data related to the factory; Data related to sterilized items only; and Data related to the importer or agent. These data are the minimum requirements for circulating the aforementioned products and allowing their import, and release of the components and inputs for their production.

(Article Three)

The chairperson of the Central Administration of Medical Devices shall issue, within five days as of the date of approving of this decree, a regulatory guideline of the procedures and rules regulating the data of label of supplies, medical and laboratory devices, diagnostic reagents and production components and inputs.

(Article Four)

This decree shall come into effect from the date of its issuance . Any other provisions that may contradict this DECREE shall be null and void.

President of the Egyptian Drug Authority

Prof. Tamer Mohamed Essam